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10/729,507	12/05/2003	Norman R. McCombs	01190.173901US	1966

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Ronald S. Kareken, Esq.  
Jaekle Fleischmann & Mugel, LLP  
Suite 200  
39 State Street  
Rochester, NY 14614-1310

EXAMINER

PATEL, MITAL B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/729,507

Applicant(s)

MCCOMBS ET AL.

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 12-15 is/are rejected.
- 7) ☒ Claim(s) 5 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/13/04
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1,2, 3, 4, 6, 7, 9, 10, 12, 13, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotliar (US 5,924,419).
5. **As to claim 1**, Kotliar teaches a compact and portable hypoxic delivery apparatus **10** by producing from ambient air (**via 13**) a product gas having a lower levels of oxygen concentration and delivering the product gas to a user of the apparatus, the apparatus comprising a pressure swing adsorption unit having at least one adsorber bed **20,21** to receive ambient air and adsorb the nitrogen or oxygen from the ambient air to produce both a nitrogen enriched gas and an oxygen enriched gas, and control

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means **22** for delivering the nitrogen enriched gas (**See Col. 4, lines 12-18**) in pulse doses to a user at selectable rates during inhalation by user.

6. **As to claim 2**, Kotliar teaches an apparatus further comprising means **37** for selectively delivering either the nitrogen enriched gas or the oxygen enriched gas to the user in pulse doses to the user.

7. **As to claim 3**, Kotliar teaches an apparatus in which the pressure swing adsorption unit comprises two adsorber beds **20,21** alternately producing the enriched gases and further comprising valve means for controlling the flow of air and gases.

8. **As to claim 4**, Kotliar teaches an apparatus further comprising means **24** for adjusting the enrichment of the nitrogen in the nitrogen enriched gas to simulate various geographic altitudes.

9. **As to claim 6**, Kotliar teaches an apparatus further comprising means **24** for adjusting the enrichment of the nitrogen in the nitrogen enriched gas to produce selectively different concentrations of oxygen and nitrogen in the nitrogen enriched gas.

10. **As to claim 7**, Kotliar teaches an apparatus in which the pressure swing adsorption unit comprises three adsorber beds alternately producing the enriched gas (**See Col. 3, lines 22-23 which disclose that the number of beds may vary which disclosure the Examiner infers to include three adsorber beds as well**).

11. **As to claim 9**, Kotliar teaches a compact and portable hypoxic delivery apparatus **10** by producing from ambient air (**via 13**) a product gas having a lower levels of oxygen concentration and delivering the product gas to a user of the apparatus, the apparatus comprising a pressure swing adsorption unit having at least one adsorber

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bed **20,21** to receive ambient air and adsorb the nitrogen or oxygen from the ambient air to produce both a nitrogen enriched gas and an oxygen enriched gas, and means **22** for selectively delivering either the nitrogen enriched gas or the oxygen enriched gas to a user during inhalation by user.

12. **As to claim 10**, Kotliar teaches an apparatus further comprising control means **37** for delivering the nitrogen enriched gas in pulse doses to the user at selectable rates during inhalation by the user.

13. **As to claim 12**, Kotliar teaches an apparatus in which the pressure swing adsorption unit comprises two adsorber beds **20,21** alternately producing the enriched gases and further comprising valve means for controlling the flow of air and gases.

14. **As to claim 13**, Kotliar teaches an apparatus further comprising means **24** for adjusting the enrichment of the nitrogen in the nitrogen enriched gas to simulate various geographic altitudes.

15. **As to claim 14**, Kotliar teaches an apparatus further comprising means **24** for adjusting the enrichment of the nitrogen in the nitrogen enriched gas to produce selectively different concentrations of oxygen and nitrogen in the nitrogen enriched gas.

16. **As to claim 15**, Kotliar teaches an apparatus in which the pressure swing adsorption unit comprises three adsorber beds alternately producing the enriched gas (See Col. 3, lines 22-23 which disclose that the number of beds may vary which disclosure the Examiner infers to include three adsorber beds as well).

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***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kotliar (US 5,924,419).

21. **As to claim 8**, Kotliar teaches essentially all of the limitations except for the apparatus further comprising means for powering the apparatus from any one of three sources including a rechargeable battery pack, an AC adapter for connection to an AC outlet, and a DC adapter for connection to the power system of a vehicle. However, it should be noted that the Kotliar makes use of a compressor draw in ambient air, the compressor being disclosed to require low wattage. Furthermore, the apparatus is disclosed for being used in medical facilities and as a home-use device. As a result, it would be obvious to one of ordinary skill in the art at the time of the invention based on the disclosure of Kotliar to provide the recited means for powering the apparatus since the use of such powering means are well known in the art to serve as back-up power source.

***Allowable Subject Matter***

22. Claims 5 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach nor render obvious the overall claimed combination of a hypoxic gas delivery apparatus in which the control means actuates the flow of delivered gas upon initial inhalation and further comprises means for increasing or decreasing the effective flow rate of breathing the nitrogen enriched gas by increasing or decreasing the activation time during each inhalation cycle.


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24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6820619, US 6796307, US 6701923, US 6694969, US 6558451, US 6561185, US 6089229, US 6009870, US 5988161, US 5871564, US 5531807, US 5383448, US 5207623, US 5101819, US 4802899, US 4086923, and US 3680557.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 11/28/04  
Mital B. Patel  
Examiner  
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